

## **REMARKS/ARGUMENTS**

### **The Status of the Claims.**

Claims 1 to 23 are pending with entry of this amendment. Claims 1 and 5 are amended herein. These amendments introduce no new matter and support is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

With respect to claim 1, support for chemically derivatising amino acid residues can be found throughout the specification. For example, see the specification at the paragraph starting at page 17, line 6, and the paragraph starting at page 22, line 9.

With respect to claim 5, support for stacking of antibodies can be found throughout the specification. For example, see the specification at page 4, line 27; the paragraph starting at page 6, line 16; the paragraph starting at page 19, line 31; and, page 21, lines 10 to 23.

Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

### **35 U.S.C. §112, Second Paragraph.**

Claims 5 and 6 were rejected under 35 U.S.C. §112, second paragraph, as allegedly vague and indefinite as unclear about what limitations differentiate antibodies that associate from those that do not. Although Applicant believes the association is clearly described in the above cited specification text, the "Association" terminology has been deleted from claim 5 and replaced with the well characterized "stack" term to enhance the clarity of claims 5 and 6.

Antibodies that stack at the site of an immobilised IgG can be precisely differentiated from antibodies that fail to stack by referring to descriptions of stacking in the specification.

For example, in the paragraph starting at page 6, line 16, Applicant describes stacking as binding associations between derivatised antibodies, and/or between derivatised antibodies and immobilised IgG. Antibodies that do not exhibit the described stacking associations, e.g., can be considered the "antibodies which do not so stack" of the currently amended claim 5. Embodiments of stacking are further described in the paragraph starting at page 19, line 31, and in Figure 8, wherein molecules of a derivatised antibody are shown stacking in binding association with other molecules of the derivatised antibody and/or with immobilized IgG molecules. Again, the specification has described stacking antibodies to clearly differentiate stacking antibodies from antibodies that do not stack. This, and other support in the specification has allowed Applicants to particularly point out and distinctly claim the subject matter regarded as his invention in currently amended claim 5 and claim 6.

As the material cited as indefinite has been replaced in the current set of claims, Applicant respectfully requests withdrawal of 35 U.S.C. §112, second paragraph rejection of claims 5 and 6.

**35 U.S.C. §102.**

Claims 1 and 2 were rejected under 35 U.S.C. §102(b) as allegedly alternately anticipated by O'Shannessy or Bieniarz.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention.

With respect to claims 1 and 2, in order for a reference to anticipate an invention, anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." Kalman v. Kimberly-Clark Corp., 218 USPQ 781, 789 (Fed. Cir. 1983). Applicant respectfully submits that all the limitations of the rejected claims, as currently amended, are not found in either of the cited references.

Currently amended claim 1 provides methods of chemically derivatising amino acid residues of the antibody. The cited references fail to describe at least this limitation. Applicant describes derivatising antibodies at amino acid residues, e.g., at page 22, line 15. O'Shannessy, in the summary on page 273 and in the methods on page 274, describes

derivatisations of antibodies involving oxidation of carbohydrate moieties with periodate. Bieniarz cites O'Shannessy (e.g., column 5, line 52) and bases his antibody derivatisations on oxidation of the carbohydrates of immunoglobulins. Neither cited reference teaches derivatisations of the instant invention wherein carbohydrate chains of the immunoglobulin are prevented from returning to interstitial sites by derivatisation of amino acid residues.

Treatment of the antibody to expose carbohydrate chains is another limitation of claim 1 that is not present in the cited references. In Example 1 of Bieniarz (column 10, line 32) cited by the Examiner, derivatisation of antibody carbohydrate takes place at 5°C in the dark. At page 274 of O'Shannessy, cited by the Examiner, derivatisation with periodate takes place at 0°C. Cited references teach derivatisations without significant physical or chemical denaturants to expose antibody carbohydrates from interstitial sites. As the cited references fail to teach treating of the antibody to expose carbohydrate chains, they can not anticipate claim 1.

As all the limitations found in claim 1, as currently amended, are not present in the cited references, Applicant respectfully requests that rejections based on 35 U.S.C. §102 anticipation be withdrawn and claim 1 be found allowable as currently amended. Claim 2 (as well as other pending dependent claims 3, 4, 5, and 6), is dependent on novel amended claim 1, and therefore has all the limitations of claim 1, and can not be anticipated by the cited art. Applicant respectfully requests that that the claims be found allowable.

#### **The Drawings.**

New drawings are provided herein to overcome objections of the draftsman. No new matter has been added in these new drawing sheets.

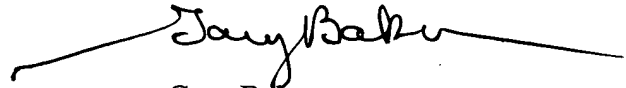
#### **CONCLUSION**

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 510-769-3510.

Appl. No. 09/622,253  
Amdt. Dated March 26, 2004

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gary Baker", is written over a horizontal line.

Gary Baker  
Reg. No: 41,595

Attachments:

- 1) A petition to extend the period of response for 1 month;
- 2) A transmittal sheet;
- 3) A fee transmittal sheet;
- 4) Replacement Drawing Sheet(s)
- 5) Annotated Drawing Sheet(s) Showing Changes
- 6) A receipt indication postcard.

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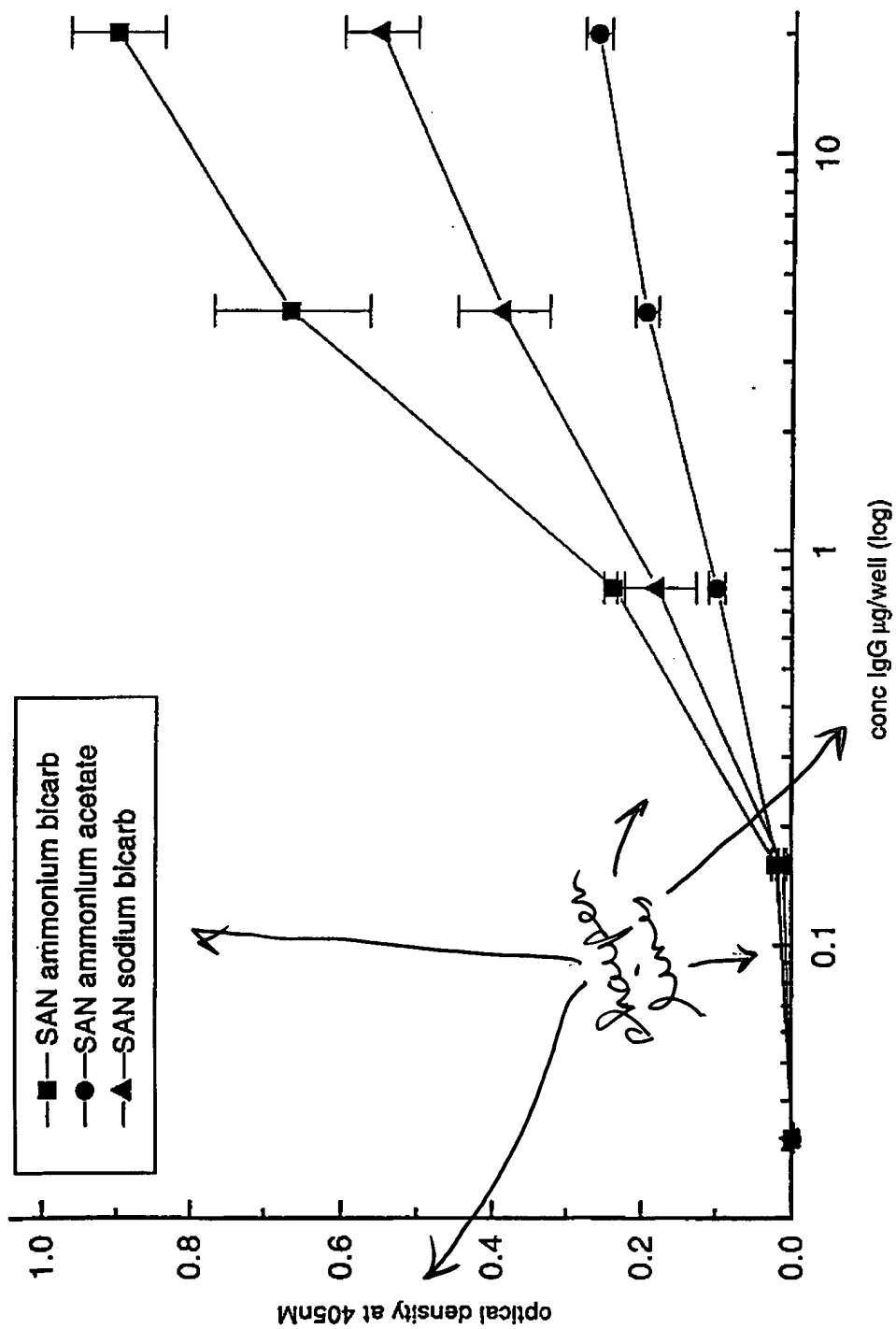
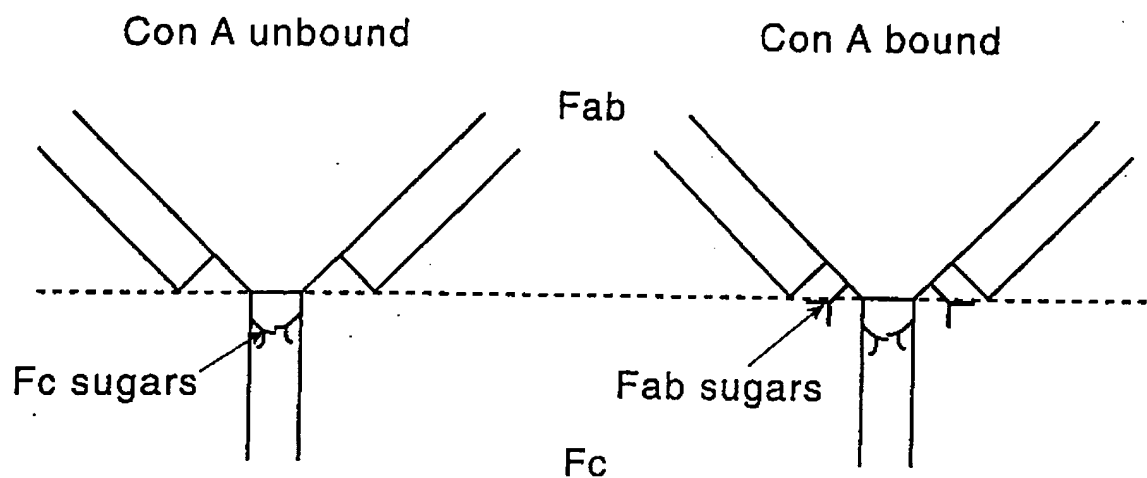


Figure 5



increase  
→  
margin

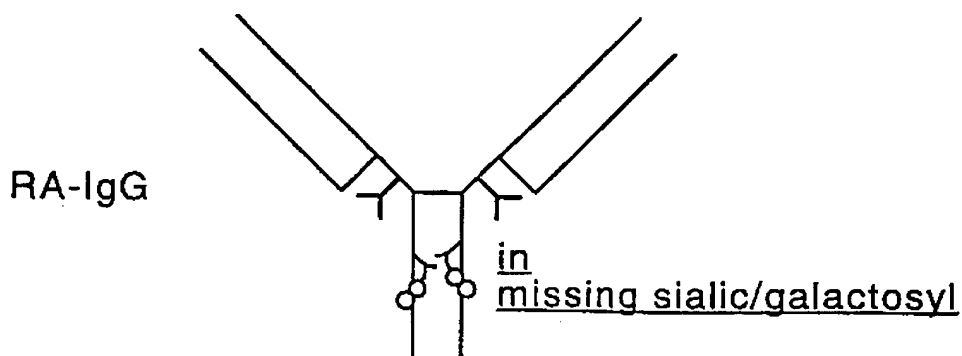
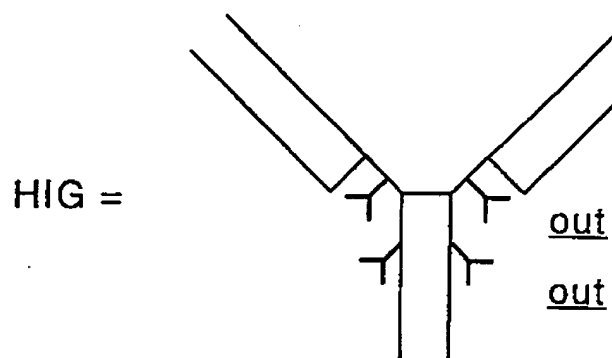


Figure 7

Figure 9

# Sugar Chains of Derivatised IgG (HIG) Become Exposed at Physiological Temperature

